IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, ALEMBIC PHARMACEUTICALS, INC., MACLEODS PHARMACEUTICALS LTD., MACLEODS PHARMA USA, INC., NATCO PHARMA LIMITED, NATCO PHARMA, INC., Defendants.	C.A. No. 1:19-cv-02021-LPS

DEFENDANTS MACLEODS PHARMACEUTICALS LTD. AND MACLEODS PHARMA USA, INC.'S ANSWER AND COUNTERCLAIMS

Defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, "Macleods"), by and through their attorneys, answer the Complaint filed by Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") as follows:

AS TO THE NATURE OF THE ACTION

1. This is a patent infringement action arising under Title 35 of the United States Code and concerning Abbreviated New Drug Applications ("ANDAs") submitted to the United States Food and Drug Administration ("FDA") by the above-named defendants seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of sacubitril/valsartan tablets, generic versions of Novartis's ENTRESTO® tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg, prior to the expiration of U.S. Patents Nos. 8,101,659 (the

"'659 patent"), 8,796,331 (the "'331 patent"), 8,877,938 (the "'938 patent"), and/or 9,388,134 (the "'134 patent").

ANSWER:

Macleods admits that Novartis purports to bring this action under the patent laws of the United States and under the Federal Declaratory Judgment Act. Macleods admits that it has submitted ANDA No. 213728 seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Macleods ANDA Products") prior to the expiration of the '659, '938, and '134 patents. Macleods denies any patent infringement as alleged by Novartis. Macleods lacks sufficient information to determine the truth or falsity of any remaining allegations in Paragraph 1 of the Complaint and on that basis denies them.

AS TO THE PARTIES[1]

2. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in East Hanover, New Jersey.

ANSWER:

Macleods lacks sufficient information to determine the truth or falsity of the allegations in Paragraph 2 of the Complaint and on that basis denies them.

17. On information and belief, Macleods Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India 400059.

[1] Paragraphs 3-16 and 27-36 of the Complaint do not state allegations against Macleods, and therefore no response to those paragraphs is required.

ANSWER:

Admitted.

18. On information and belief, Macleods Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at Incorp Services, Inc., 919 North Market Street, Suite 950, Wilmington, Delaware 19801, and having a principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536. On information and belief, Macleods Pharma USA, Inc. is a wholly owned subsidiary of Macleods Pharmaceuticals Ltd.

ANSWER:

Admitted.

19. On information and belief, Macleods Pharmaceuticals Ltd. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

ANSWER:

Macleods admits that Macleods Pharmaceuticals Ltd., among other things, develops and manufactures drug products. Macleods denies the remaining allegations of Paragraph 19.

20. On information and belief, Macleods Pharma USA, Inc. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

ANSWER:

Macleods admits that Macleods Pharma USA, Inc. sells drug products for the United States market. Macleods denies the remaining allegations of Paragraph 20.

21. By a letter dated September 11, 2019 ("Macleods Notice Letter"), Macleods Pharmaceuticals Ltd. notified Novartis that (i) Macleods Pharmaceuticals Ltd. had submitted to the FDA ANDA No. 213728 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Macleods ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '938, and '134 patents, and that (ii) ANDA No. 213728 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '938, and '134 patents.

ANSWER:

Admitted.

22. Macleods Pharmaceuticals Ltd. has committed an act of infringement in this judicial district by filing ANDA No. 213728 with the intent to make, use, sell, offer for sale, and/or import the Macleods ANDA Products in or into this judicial district, prior to the expiration of the '659, '938, and '134 patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

ANSWER:

Denied.

23. On information and belief, Macleods Pharma USA, Inc. acted in concert with and under the direction of Macleods Pharmaceuticals Ltd. in the preparation and submission of ANDA No. 213728, and, if the ANDA is approved, will act in concert with and under the direction of Macleods Pharmaceuticals Ltd. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '938, and '134 patents.

ANSWER:

The allegations of Paragraph 23 state legal conclusions that do not require a response. Macleods admits that Macleods Pharmaceuticals Ltd. acted to prepare and submit ANDA No. 213728. Macleods lacks knowledge or information sufficient to form a belief as to the allegations concerning future conduct and therefore denies them. Macleods denies the remaining factual allegations of Paragraph 23.

24. Macleods Pharmaceuticals Ltd., by itself or together with Macleods Pharma USA, Inc., has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Macleods ANDA Products, that will be purposefully directed at Delaware and elsewhere.

ANSWER:

Macleods admits that Macleods Pharmaceuticals Ltd. has prepared and submitted ANDAs to the FDA. Macleods lacks knowledge or information sufficient to form a belief as to the allegations concerning future conduct and therefore denies them. Macleods denies the remaining factual allegations of Paragraph 24.

25. On information and belief, Macleods Pharmaceuticals Ltd. has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including Macleods Pharma USA, Inc.; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

ANSWER:

Macleods denies the allegations of Paragraph 25 as phrased but does not contest personal jurisdiction over Macleods Pharmaceuticals Ltd. in this Court for the purposes of this civil litigation only.

26. Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See*, *e.g.*, *Merck Sharp & Dohme Corp. v. Macleods Pharms. Ltd. et al.*, C.A. No. 19-316 (D. Del.).

ANSWER:

Macleods denies the allegations of Paragraph 26 as phrased but does not contest personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only.

JURISDICTION AND VENUE[2]

37. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER:

Admitted.

45. This Court has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. because, on information and belief, each such Defendant has committed or has aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting ANDA No. 213728 with a certification

[2] Paragraphs 38-44 and 51-56 of the Complaint do not state allegations against Macleods, and therefore no response to those paragraphs is required.

pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Novartis, a Delaware corporation.

ANSWER:

Macleods denies the allegations of patent infringement and denies the remaining allegations of Paragraph 45 as phrased. However, Macleods does not contest personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only.

46. This Court also has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. because, on information and belief, each such Defendant, upon approval of ANDA No. 213728, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213728 that will be purposefully directed at Delaware, including the marketing of the Macleods ANDA Products in Delaware, prior to the expiration of the ’659, ’938, and ’134 patents.

ANSWER:

Macleods denies the allegations of patent infringement and denies the remaining allegations of Paragraph 46 as phrased. However, Macleods does not contest personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only.

47. This Court also has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. because, on information and belief, each such Defendant’s affiliations with the State of Delaware, including Macleod Pharma USA, Inc.’s incorporation in Delaware, and Macleods Pharmaceuticals Ltd.’s ownership of and actions in concert with

Macleods Pharma USA, Inc., are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

ANSWER:

Macleods denies the allegations of Paragraph 45 as phrased but does not contest personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only.

48. This Court also has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. because Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. have availed themselves of the legal protections of the State of Delaware, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

ANSWER:

Macleods denies the allegations of Paragraph 48 as phrased but does not contest personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only.

49. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.

ANSWER:

Macleods denies the allegations of Paragraph 49 as phrased but does not contest personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only.

50. Venue is proper in this Court because Macleods Pharma USA, Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and Macleods Pharmaceuticals Ltd. is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3).

ANSWER:

Paragraph 48 contains legal conclusions that do not require a response. Macleods does not contest that venue is proper in this Court for the purposes of this civil litigation only.

AS TO THE PATENTS-IN-SUIT AND ENTRESTO®

51. Novartis is the owner of the ’659 patent, titled “Methods of treatment and pharmaceutical composition.” The ’659 patent was duly and legally issued on January 24, 2012. A true and correct copy of the ’659 patent is attached hereto as Exhibit A.

ANSWER:

Macleods admits that the ’659 patent issued on January 24, 2012 and is entitled “Methods of treatment and pharmaceutical composition.” Macleods admits that the U.S. Patent and Trademark Office’s assignment database lists Novartis as the assignee of the ’659 patent and that what appears to be a copy of the ’659 patent was attached as Exhibit A to the Complaint. Macleods denies that the ’659 patent was duly and legally issued.

52. The ’659 patent claims, inter alia, a pharmaceutical composition comprising (i) valsartan or a pharmaceutically acceptable salt thereof; (ii) sacubitril or sacubitrilat or a pharmaceutically acceptable salt thereof; and (iii) a pharmaceutically acceptable carrier; wherein (i) and (ii) are administered in combination in about a 1:1 ratio.

ANSWER:

The allegations of Paragraph 52 state legal conclusions that do not require a response. To the extent that there are any remaining factual allegations in Paragraph 52, Macleods states that the claims of the '659 patent speak for themselves.

53. Novartis is the owner of the '331 patent, titled "Methods of treatment and pharmaceutical composition." The '331 patent was duly and legally issued on August 5, 2014. A true and correct copy of the '331 patent is attached hereto as Exhibit B.

ANSWER:

Macleods admits that the '331 patent issued on August 5, 2014 and is entitled "Methods of treatment and pharmaceutical composition." Macleods admits that the U.S. Patent and Trademark Office's assignment database lists Novartis as the assignee of the '331 patent and that what appears to be a copy of the '331 patent was attached as Exhibit B to the Complaint. Macleods denies that the '331 patent was duly and legally issued.

54. The '331 patent claims, inter alia, a method for the treatment of heart failure or hypertension, comprising administering to a patient in need thereof a therapeutically effective amount of the combination of (i) valsartan or a pharmaceutically acceptable salt thereof; and (ii) sacubitril or sacubitrilat or a pharmaceutically acceptable salt thereof; wherein (i) and (ii) are administered in one unit dose form or in two separate unit dose forms.

ANSWER:

The allegations of Paragraph 54 state legal conclusions that do not require a response. To the extent that there are any remaining factual allegations in Paragraph 54, Macleods states that the claims of the '331 patent speak for themselves.

55. Novartis is the owner of the ’938 patent, titled “Compounds containing S-N-valeryl-N-{[2′-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine and (2R,4S)-5-biphenyl-4-yl-4-(3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester moieties and cations.” The ’938 patent was duly and legally issued on November 4, 2014. A true and correct copy of the ’938 patent is attached hereto as Exhibit C.

ANSWER:

Macleods admits that the ’938 patent issued on November 4, 2014 and is entitled “Compounds containing S-N- valeryl-N-{[2′-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine and (2R,4S)-5-biphenyl-4-yl-4- (3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester moieties and cations.” Macleods admits that the U.S. Patent and Trademark Office’s assignment database lists Novartis as the assignee of the ’938 patent and that what appears to be a copy of the ’938 patent was attached as Exhibit B to the Complaint. Macleods denies that the ’938 patent was duly and legally issued.

56. The ’938 patent claims, inter alia, trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl)propionate-(S)-3′-methyl-2′-(pentanoyl{2″-(tetrazol-5-ylate)biphenyl-4′-ylmethyl}amino)butyrate] hemipentahydrate (“sacubitril/valsartan trisodium hemipentahydrate complex”) in crystalline form.

ANSWER:

The allegations of Paragraph 56 state legal conclusions that do not require a response. To the extent that there are any remaining factual allegations in Paragraph 56, Macleods states that the claims of the ’938 patent speak for themselves.

57. Novartis is the owner of the ’134 patent, titled “Compounds containing S-N-valeryl-N-{[2′-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine and (2R,4S)-5-biphenyl-4-yl-4-

(3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester moieties and cations." The '134 patent was duly and legally issued on July 12, 2016. A true and correct copy of the '134 patent is attached hereto as Exhibit D.

ANSWER:

Macleods admits that the '134 patent issued on July 12, 2016 and is entitled "Compounds containing S-N- valeryl-N-{[2′-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine and (2R,4S)-5-biphenyl-4-yl-4- (3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester moieties and cations." Macleods admits that the U.S. Patent and Trademark Office's assignment database lists Novartis as the assignee of the '134 patent and that what appears to be a copy of the '134 patent was attached as Exhibit D to the Complaint. Macleods denies that the '134 patent was duly and legally issued.

58. The '134 patent claims, inter alia, a method for the treatment of heart failure or hypertension, in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex.

ANSWER:

The allegations of Paragraph 58 state legal conclusions that do not require a response. To the extent that there are any remaining factual allegations in Paragraph 58, Macleods states that the claims of the '134 patent speak for themselves.

59. Novartis is the holder of New Drug Application ("NDA") No. 207620 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of ENTRESTO® (sacubitril and valsartan) tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg. ENTRESTO® currently is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and

reduced ejection fraction, and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

ANSWER:

Macleods admits that Novartis is the holder of NDA No. 207620 relating to ENTRESTO® tablets. As to the factual allegations pertaining to the current indications for ENTRESTO®, Macleods states that NDA No. 207620 speaks for itself. As to any remaining factual allegations in Paragraph 59, Macleods is without sufficient information to form a belief as to the truth or falsity of the allegations and on that basis denies them.

60. One or more claims of each of the '659, '331, '938, and '134 patents cover ENTRESTO® and/or the use thereof.

ANSWER:

Paragraph 60 states legal conclusions as to which no response is required. To the extent that there are any remaining factual allegations in Paragraph 60, Macleods lacks sufficient information to form a belief as to the truth or falsity of those allegations and on that basis denies them.

61. The FDA's official publication of approved drugs (the "Orange Book") lists the '659, '331, '938, and '134 patents in connection with ENTRESTO®.

ANSWER:

Admitted.

AS TO INFRINGEMENT BY EACH DEFENDANT OF THE PATENTS-IN-SUIT[3]

62. Novartis incorporates paragraphs 1 – 36 and 57 – 67 as if fully set forth herein.

[3] Paragraphs 63-74 and 88-103 of the Complaint do not state allegations against Macleods, and therefore no response to those paragraphs is required.

ANSWER:

Macleods incorporates its responses to paragraphs 1-36 and 57-67.

75. On information and belief, Macleods Pharmaceuticals Ltd., by itself or in concert with Macleods Pharma USA, Inc., submitted to the FDA ANDA No. 213728 under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products prior to the expiration of the '659, '938, and '134 patents.

ANSWER:

Macleods admits that Macleods Pharmaceuticals Ltd. submitted ANDA No. 213728 to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Macleods ANDA products prior to the expiration of the '659, '938, and '134 patents. Macleods denies the remaining factual allegations of Paragraph 75.

76. This action was commenced within 45 days of Novartis's receipt of the Macleods Notice Letter.

ANSWER:

Admitted.

77. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States prior to the expiration of the '659, '938, and '134 patents, Macleods Pharmaceuticals Ltd., and, on information and belief, Macleods Pharma USA, Inc., have committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER:

Denied.

78. On information and belief, when Macleods Pharmaceuticals Ltd. filed ANDA No. 213728, Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. were aware of the '659, '938, and '134 patents and that the filing of the ANDA with the request for its approval prior to the expiration of the '659, '938, and '134 patents was an act of infringement of those patents.

ANSWER:

Macleods admits that Macleods Pharmaceuticals Ltd. was aware of the '659, '938, and '134 patents when Macleods Pharmaceuticals Ltd. filed ANDA No. 213728. Macleods denies the remaining allegations of Paragraph 78.

79. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States will infringe one or more claims of the '659, '938, and '134 patents.

ANSWER:

Denied.

80. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States will directly infringe one or more claims of the '659 patent.

ANSWER:

Denied.

81. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States will directly infringe one more claims of the ’938 patent.

ANSWER:

Denied.

82. On information and belief, the Macleods ANDA Products, if approved, will contain instructions for practicing a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, which administration will constitute direct infringement of one or more claims of the ’134 patent. On information and belief, if the Macleods ANDA Products are approved, physicians and/or patients following said instructions will directly infringe one or more claims of the ’134 patent. On information and belief, if the Macleods ANDA Products are approved, Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, Inc. will actively encourage, recommend, or promote this infringement with knowledge of the ’134 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’134 patent.

ANSWER:

Denied.

83. On information and belief, if the Macleods ANDA Products are approved, Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, Inc. will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled for use in a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium

hemipentahydrate complex, as recited in one or more claims of the ’134 patent. On information and belief, if the Macleods ANDA Products are approved, those products will constitute a material part of a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, as recited in one or more claims of the ’134 patent. On information and belief, if the Macleods ANDA Products are approved, physicians and/or patients following the instructions in the Macleods ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Macleods ANDA Products are approved, Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, Inc. will contributorily infringe one or more claims of the ’134 patent, and will do so with knowledge of the ’134 patent, and that the Macleods ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’134 patent and are not suitable for a substantial noninfringing use.

ANSWER:

Denied.

84. Novartis will be substantially and irreparably damaged by Macleods Pharmaceuticals Ltd.’s and/or Macleods Pharma USA, Inc.’s infringement of the ’659, ’938, and ’134 patents.

ANSWER:

Denied.

85. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 213728 be a date that is no earlier than July 14, 2023, the expiration of the ’659 patent’s pediatric exclusivity, November 27, 2027, the expiration date of the ’938 patent’s pediatric exclusivity, and May 8, 2027, the

expiration of the ’134 patent’s pediatric exclusivity, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Macleods ANDA Products and any act committed by Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, Inc. with respect to the subject matter claimed in the ’659, ’938, and ’134 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

ANSWER:

Denied.

86. On information and belief, Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products, including seeking approval of those products under ANDA No. 213728.

ANSWER:

Macleods admits that Macleods Pharmaceuticals Ltd. filed ANDA No. 213728 seeking approval to manufacture, use, offer for sale, and/or import the Macleods ANDA products. Macleods denies the remaining allegations of Paragraph 86.

87. There is a substantial and immediate controversy between Novartis and Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. concerning the ’659, ’938, and ’134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. will infringe, induce infringement of, and/or contributorily infringe one or more claims of the ’659, ’938, and ’134 patents.

ANSWER:

Macleods admits that there is a substantial and immediate controversy between Novartis and Macleods concerning the '659, '938, and '134 patents. Macleods denies the remaining allegations of Paragraph 87.

RESPONSE TO PRAYER FOR RELIEF

Macleods denies that Novartis is entitled to the judgment or other relief prayed for in Paragraphs 112-119 of the Complaint under the heading PRAYER FOR RELIEF. The remaining paragraphs under that heading do not relate to allegations against Macleods, and no response to those paragraphs is required.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

Novartis fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

Novartis fails to state any facts to support a claim upon which relief may be granted.

THIRD AFFIRMATIVE DEFENSE

Each asserted claim of the '659, '938, and '134 patents is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116 and/or is invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity.

FOURTH AFFIRMATIVE DEFENSE

Macleods has not infringed, induced infringement of, or contributed to the infringement of, and Macleods will not infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable asserted claim of the '659, '938, and '134 patents, either literally or under the doctrine of equivalents, through the submission of Macleods' ANDA No. 213728

and/or the importation, manufacture, use, offer for sale or sale of the product that is the subject of Macleods' ANDA No. 213728.

SIXTH AFFIRMATIVE DEFENSE

Novartis is not entitled to injunctive relief against Macleods because Novartis' alleged damages are not immediate or irreparable, and therefore Novartis has an adequate remedy at law. Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

SEVENTH AFFIRMATIVE DEFENSE

Novartis is not entitled to attorney's fees against Macleods because Novartis has not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285.

EIGHTH AFFIRMATIVE DEFENSE

35 U.S.C. § 288 prevents Novartis from recovering any costs associated with this action.

NINTH AFFIRMATIVE DEFENSE

Novartis' allegations are barred, in whole or in part, by the doctrines of waiver, estoppel and/or prosecution history estoppel.

TENTH AFFIRMATIVE DEFENSE

Macleods reserves the right to assert additional affirmative defenses that may be developed or revealed during discovery.

COUNTERCLAIMS

In further response to the Complaint, Macleods alleges the following counterclaims, without prejudice to any denial in its Answer, and without admission to any allegation in the

Complaint, unless otherwise explicitly admitted above, and without assuming any burden when such burden would otherwise belong to Novartis.

Parties

1. Counterclaimant Macleods Pharmaceuticals Limited is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Atlanta Arcade, Marol Church, Andheri (East), Mumbai, India 400059.

2. Counterclaimant Macleods Pharma USA, Inc. (collectively, both entities are referred to herein as "Macleods") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536.

3. Upon information and belief, Counterclaim Defendant Novartis Pharmaceuticals Corporation ("Novartis") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in East Hanover, New Jersey.

Jurisdiction and Venue

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367, 2201, and 2202. Macleods' counterclaims relate to the claims made by Counterclaim Defendant Novartis for patent infringement and arise under the patent laws of the United States, Title 35, United States Code.

5. This Court has personal jurisdiction over Novartis because it is organized under the law of the State of Delaware, conducts business in the State of Delaware, has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with Delaware.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) and by Counterclaim Defendant Novartis' filing of its action against Macleods. This Court may declare the rights and legal relation of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5).

The Controversy

7. Macleods holds Abbreviated New Drug Application ("ANDA") No. ANDA No. 213728 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg.

8. On or about October 24, 2019, Counterclaim Defendant Novartis filed the present action against Macleods alleging infringement of United States Patent Nos. 8,101,659 (the "'659 patent"), 8,796,331 (the "'331 patent"), and 8,877,938 (the "'938 patent"). There is a real, substantial, and continuing justiciable controversy between the parties because of the commencement by Counterclaim Defendant of its action and the filing by Macleods of ANDA No. 213728 with certifications that the '659, '938, and '331 patents are invalid, unenforceable and/or will not be infringed by the manufacture, sale and use of the products of Macleods' ANDA No. 213728.

9. The patents-in-suit effectively prevent approval of Macleods' ANDA Nos. 213728 and the manufacture, sale, and use of the products that are the subject of Macleods' ANDA No. 213728. Macleods and Novartis have adverse legal interests with respect to the patents-in-suit of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

COUNT I

Declaratory Judgment of Invalidity of the '659 Patent

10. Macleods repeats and incorporates by reference paragraphs 1 to 9 of their Counterclaims as if fully set forth herein.

11. Each and every asserted claim of United States Patent No. 8,101,659 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT II

Declaratory Judgment of Invalidity of the '331 Patent

12. Macleods repeats and incorporates by reference paragraphs 1 to 9 of their Counterclaims as if fully set forth herein.

13. Each and every asserted claim of United States Patent No. 8,796,331 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT III

Declaratory Judgment of Invalidity of the '938 Patent

14. Macleods repeats and incorporates by reference paragraphs 1 to 9 of their Counterclaims as if fully set forth herein.

15. Each and every asserted claim of United States Patent No. 8,877,938 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code,

including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT IV

Declaratory Judgment of Noninfringement of the ’659 Patent

16. Macleods repeats and incorporates by reference paragraphs 1 to 9 of their Counterclaims as if fully set forth herein.

17. Macleods has not infringed, induced infringement, or contributed to the infringement, and Macleods will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 8,101,659.

COUNT V

Declaratory Judgment of Noninfringement of the ’331 Patent

18. Macleods repeats and incorporates by reference paragraphs 1 to 9 of their Counterclaims as if fully set forth herein.

19. Macleods has not infringed, induced infringement, or contributed to the infringement, and Macleods will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 8,796,331.

COUNT VI

Declaratory Judgment of Noninfringement of the ’938 Patent

20. Macleods repeats and incorporates by reference paragraphs 1 to 9 of their Counterclaims as if fully set forth herein.

21. Macleods has not infringed, induced infringement, or contributed to the infringement, and Macleods will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 8,877,938.

Macleods' Request for Relief

WHEREFORE, Macleods respectfully requests that:

(a) Judgment be entered that the Complaint against Macleods is dismissed with prejudice and that Plaintiffs/Counterclaim Defendants take nothing thereby;

(b) Judgment be entered that each claim of United States Patent Nos. 8,101,659, 8,796,331, and 8,877,938 is invalid;

(c) The Court permanently enjoin Plaintiff/Counterclaim Defendant or any of its assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Macleods' ANDA No. 213728 infringe or will infringe any valid claim of U.S. Patent Nos. 8,101,659, 8,796,331, and/or 8,877,938.

(d) This case be deemed an exceptional case within the meaning of 35 U.S.C. § 285.

(e) Macleods be awarded its reasonable costs and attorney fees; and

(f) The Court award Macleods such other and further relief as this Court may deem necessary, just and proper.

Respectfully submitted,

/s/ John M. Seaman

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